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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,621	12/30/2003	Ali R. Rezai	26336-10067	8232
26294 7590 02/21/2008 TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVEVLAND, OH 44114				
EXAMINER				
ALTER, ALYSSA M				
ART UNIT		PAPER NUMBER		
3762				
MAIL DATE		DELIVERY MODE		
02/21/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/749,621

Applicant(s)

REZAI ET AL.

Examiner

ALYSSA M. ALTER

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 10-12, 15 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 10-12, 15 and 18-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed June 28, 2007 have been fully considered but they are not persuasive.

Furthermore, the Applicant also argues that "the lead" is positively recited by recitation in the preamble. The examiner would again like to clarify the rejection "It is unclear whether the Applicant **intends to claim the use of a specific lead with the retaining device or is merely claiming the retaining device.**" The examiner is not rejecting the claim under antecedent basis for recitation of a lead, but indicating that it is unclear if there is a specific lead claimed in conjunction with the system or if the device is merely capable of employment with any lead.

Furthermore, the Applicant argues that Singhal et al. does not teach a flange with a plurality of grooves. However, the examiner considered the flange to be the ring member 142. This flange 142 also includes the core of the burr hole cap. Therefore the flange is the portions of the cap that also engulfs the groove 146. Therefore, the flange does have a plurality of grooves.

Additionally, the claim preamble only states "for....a lead" and there is only functionally reciting the lead and not positively reciting the lead. As such, any lead retainer that has a plurality of grooves, such as Singhal, will inherently meet the limitation of the groove being smaller than the lead since the lead has not been positively recited and the lead is a relative size.

Additionally, the Applicant argues that Singhal et al. does not provide a spiral groove. However, the claim recites the limitations "spiral groove dimensioned such that the excess portion of the lead can be stored in at least one loop in the spiral groove". Depicted to the right is the path of at least one loop of excess lead. The lead is stored in a spiral pattern and thus the groove as disclosed by Singhal et al. is a spiral groove.

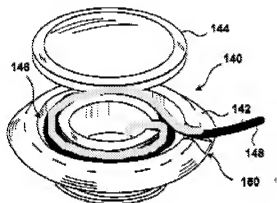


FIG. 8

As to the Applicant arguments in regards to amended claims 22-23, Singhal et al. does in fact depict spaced apart grooves as shown in figure 8 in accordance with the rejection below.

Therefore the claims remain rejected under 35 U.S.C. 112 and Singhal et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 1 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant, in claims 1, 22, 36 and 41, does not positively recite the inclusion of a lead with the system for retaining a lead, but merely inferentially includes the use of a lead. It is unclear whether the Applicant intends to claim the use of a specific lead with the retaining device or is merely claiming the retaining device.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 12, 15, 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Singhal et al. (US Patent Publication 20050004637 A1). Singhal et al. discloses a burr hole cap with a lead management system as depicted in figure 8.

As to claim 12, the ring member 142 is considered to be a flange. The examiner considers the walls of groove or exit 150 to be tabs. As depicted in the replica of figure 8 to the right, the wall label "A" is one of the tabs. The two tabs, or walls create the exit 150. Furthermore, the examiner also considers the inner core of the burr

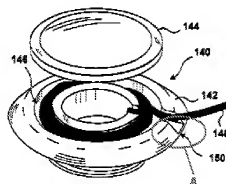


FIG. 8

hole cap to also possess tabs, with similar groove/tab structure as stated above.

As to claims 12 and 22-23, Additionally there is a plurality of grooves, the inside groove 146 and exit 150, which the examiner considers to be a groove. Also, the cut out in the core of the burr hole cap, where the lead enters the cap is also considered to be a groove. Therefore these grooves are spaced apart.

As to claim 15, since the groove extends from the core of the burr hole ring to the external ring member, the examiner considers the groove to be a "spiral groove" since the groove "extends for the aperture to at least one outlet periphery of the outside surface of the burr ring".

As to claim 20, Singhal et al. discloses on page 5, paragraph 64, "Ring member 142, cover member 144 or both can be constructed from a protective material that would resist damage in the event the incision should cut across burr hole cover 140". Therefore, since the protective material would resist damage, the examiner considers it to be "resilient material".

As to claim 21, the lead can be coiled in a plurality of different coiling configurations since the lead can be coiled around the core, in a lateral manner, or coiled from the core to the outer peripheral of the ring, in a horizontal manner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 1-5, 7-8 and 10-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Singhal et al. (US Patent Publication 20050004637 A1). Singhal et al. discloses the claimed invention except for the grooves having a width less than the diameter of each lead. It would have been obvious to one having ordinary skill in the art

at the time the invention was made to modify the grooves as taught by Singhal et al. with a grooves less than the diameter of the leads to hold the leads since it was known in the art that a reduced groove would enable the pinching or locking of a lead to prevent movement of the lead while positioned within the skull.

2. Claim 1-5, 7-8 and 10-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mogg (PCT/GB03/00539, International Publication Number WO 03/068304 A1). Mogg discloses a catheter clamp and a clamping means with a retainer formed from several grooves. Mogg discloses the claimed invention except for the placement of the apparatus into a burr hole in the patient's skull to secure a lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the clamping system as taught by Mogg with a lead for placement in a burr hole, since such a modification would enable the leads to be locked in a low profile design to enable a streamline clamping to prevent movement of a lead in the skull.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alyssa M Alter/
Examiner
Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762